Government Reform Committee Flu Vaccine Shortage Investigation

On October 5, 2004, the British government's Medicines and Healthcare Products Regulatory Agency (MHRA) suspended the Chiron Corporation's influenza vaccine manufacturing license effective immediately for three months because of manufacturing problems. As a result, the U.S. will not receive the 46-48 million flu shots of Fluvirin, half of the nation's supply.

The Committee's investigation into the issues surrounding the flu vaccine shortage began at a flu pandemic hearing in February 2004 and an emergency hearing in October 2004 regarding Chiron's license suspension and the resulting flu vaccine shortage. At the February 2004 hearing, the Committee was concerned that Chiron did not have a manufacturing plant located within the U.S. Should a flu pandemic occur, it was theorized that the UK could nationalize Chiron's vaccine supply, resulting in the loss of half of the U.S. flu vaccine supply.

At the emergency hearing held on October 8, 2004, the Committee discussed contributing factors to the flu vaccine shortage, how the government and vaccine manufacturers were responding to and managing the crisis, and what steps would be taken to prepare for next year's flu season.

Chairman Davis and Ranking Member Waxman sent a letter to FDA on October 13, 2004 requesting documents that would indicate whether FDA knew about the problems at the Chiron facility and whether FDA responded adequately. The documents confirm that FDA followed routine protocol in responding to Chiron's August 26, 2004 announcement. The documents further prove that FDA had no knowledge prior to October 5, 2004 that MHRA would suspend Chiron's manufacturing license.

As part of the Committee's ongoing investigation, Chairman Davis and staff traveled to London the week of November 8 through November 12, 2004 to hold meetings with officials from MHRA and Chiron. The Committee also conducted an extensive meeting with FDA officials in Washington to discuss FDA documents and the Committee's findings from meetings held in London.

Based upon testimony from previous hearings, FDA documents, and meetings held with Chairman Davis, it appears certain that FDA followed standard protocol in dealing with Chiron's initial August 25, 2004 notification of the contamination found in the 8 lots of Fluvirin. It could be argued that because there are only two major flu manufacturers in the U.S., and because the U.S. has suffered from flu vaccine shortages in the past, FDA should have taken a more aggressive stance with Chiron. However, to date, the Committee finds no factual basis for a finding that FDA did not conduct its obligatory oversight of Chiron.

In addition, the Committee finds no evidence confirming that FDA was negligent in not reaching out to MHRA for further information regarding Chiron. It is the Committee's hope that the current open communication between FDA and MHRA will continue in the future. It stands to benefit both regulatory agencies if an appropriate agreement for information sharing regarding biologics and drug manufactures that fall under both jurisdictions can be reached and implemented.

Timeline of Government Reform Committee Activity

February 12, 2004: First Hearing – discussed possibility that if a flu pandemic occurred and the UK nationalized Chiron's vaccine supply, the U.S. would lose one half of its flu vaccine supply. With only a few vaccine manufacturers producing flu vaccines each year, the Committee concluded that appropriate steps must be taken to strengthen the market and increase production capacities.

October 8, 2004: Second Hearing – FDA and CDC testified it had no prior knowledge of MHRA's October 5 announcement suspending Chiron's license.

October 13, 2004: Letter to FDA – requested Form 483 and the Establishment Inspection Report from FDA's June 2003 inspection of the Chiron's Liverpool Fluvirin facility, copies of correspondence between FDA and MHRA, and FDA and Chiron.

October 15, 2004: Letter to FTC – requested FTC investigate the pervasiveness of flu vaccine price gauging and inquired as to what enforcement actions FTC has taken to remedy price gauging.

October 20, 2004: Deadline for FDA documents.

October 22, 2004: Letter from Ranking Member Waxman to Chairman Davis – urged Chairman Davis to subpoena FDA documents.

October 22, 2004: Letter from FDA – Dr. Crawford formally asks for additional time to respond to the Committee's documents request.

October 22, 2004: Letter from Chairman Davis to Waxman – informed Waxman his push for a subpoena was premature and explains why an extension of time was provided to FDA.

October 26, 2004: Letter from Mr. Waxman to FDA – Accused FDA of withholding documents from Congress, media, and the public that address whether the flu vaccine could have been prevented. The letter suggested FDA is holding onto documents until the end of the election.

October 27, 2004: Letter to GAO – Chairman Davis and Mr. Waxman requested GAO to review the strengths and weaknesses of the U.S. response to the current flu vaccine shortage.

November 4, 2004: Letter and Documents Production from FDA – Committee received documents from FDA. Documents included a copy of Form 483 and the Establishment Inspection Report from FDA's June 2003 inspection of the Chiron's Liverpool Fluvirin facility, copies of correspondence between FDA and MHRA, and FDA and Chiron. Documents indicate that FDA followed routine protocol in responding to Chiron's August 26, 2004 announcement. Documents confirm that FDA had no knowledge prior to October 5, 2004 that MHRA would suspend Chiron's manufacturing license.

November 8, 2004: Meeting with Medimmune – Chairman Davis and Committee staff met with Ed Arcuri, Senior Vice President of Manufacturing, in London to discuss Medimmune's response to the flu vaccine shortage, steps being taken in preparation for next year's flu season, and what incentives can be provided to manufacturers to ensure a stable annual influenza vaccine supply.

November 10, 2004: Meeting with UK Department of Health and MHRA – Chairman Davis and staff met with British health officials to discuss Chiron's license suspension. MHRA provided a summary of actions taken following Chiron's August 26, 2004 announcement that contamination was detected in 8 lots of vaccine.

November 11, 2004: Meeting with Chiron – Chairman Davis and staff met with Chiron officials in London to discuss events leading up to its license suspension. Chiron's remediation plan was also discussed.

November 15, 2004: Meeting with FDA – Committee staff met with FDA officials from the Office of Legislation and Center for Biologics Evaluation and Research. Events leading up to Chiron's license suspension was discussed along with FDA's enhanced efforts to coordinate with MHRA. FDA officials also discussed its June 2003 inspection of Chiron's Fluvirin facility in Liverpool.

November 17, 2004: Third Hearing – Chiron's CEO, Howard Pien, FDA Commissioner, Dr. Crawford, and CDC Director, Dr. Gerberding, will testify before the Committee. The hearing will examine the federal government's response to the vaccine shortage, how U.S. public health officials are coordinating with vaccine manufacturers to locate and adequately distribute available influenza vaccine to high risk populations, what steps are being taken in preparation for next year's influenza season, and what incentives can be provided to manufacturers to ensure a stable annual influenza vaccine supply.